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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,427	12/31/2003	Frank Fago	L-F/217/273	1785
<div>7590 12/12/2007 WOOD, HERRON &amp; EVANS, L.L.P. 2700 Carew Tower 441 Vine St. Cincinnati, OH 45202</div>			<div>EXAMINER VU, QUYNH-NHU HOANG</div>	
			<div>ART UNIT 3763</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 12/12/2007</div>	<div>DELIVERY MODE PAPER</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/750,427

Applicant(s)

FAGO ET AL.

Examiner

Quynh-Nhu H. Vu

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

Amendment and Request for Continued Examination (RCE) filed on 11/15/07 have been entered.

Claims 9-24 are present for examination.

Claims 1-8 are cancelled.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation "filling the syringe at a first rate wherein aeration of the contrast media is prevented" of claim 9 is vague. Does Applicant mean that "filling the syringe with the rate to avoid aerating the contrast media?"

Additionally, the limitation: "said first rate being faster than a second rate that is a maximum fill rate if air is not previously expelled from the fill tube" of claim 9 is vague and unclear. Does applicant mean that the "the first rate determined in step 910, (which is filling the syringe stage) is faster than the second rate determined in step 908, (which is stage of push/expelling all air from the fill tube)"?

Similarly, in claim 18, the limitation "wherein the filling occurs at a second rate that is faster than the first rate if the determining results in a determination that at least some of the medical fluid has been expelled from the syringe" is unclear and confusing. Again, does applicant mean that "the first rate determined in step 906, (which is pull small amount of contrast into syringe); and the second step determined in step 910, (which is filling the syringe stage)?"

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (US 5,573,515).

Regarding claims 9, as best as understood, Wilson discloses a method comprising: the step of expelling substantially all air from the fill tube (any air ejected, coll. 2, line 11), thereafter, filling the syringe at the first rate. It is noted that user may adjust rate, furthermore there is a flow rate display, 264, and evidence that the flow rate is changed at col. 12, lines 20-22; wherein aeration of the contrast media is prevented (contrast fill operation repeated, col. 5, line 63); the first rate being faster than a second rate (flow rate changeable, col. 11, lines 25-30 or col. 12 lines 20-22). Because the air being light than the contrast material, gathers near the top of syringe body. Therefore, the second rate of the step of expelling all air from the fill tube/syringe, including some medical fluid expelled from syringe must be slowly occur. For example, if the user applies big force, the plunger moves fast, (which is the rate of flow increased also), there will be air and all medical fluid/contrast material move out the syringe/fill tube which is the user does not want. Hence, the first rate is faster than the second rate. Wilson further discloses that flow rate changeable (col. 11, lines 25-30 or col. 12, lines 20-22). Therefore, one skill in the art would recognize that the first rate can be faster than second rate if the user wants to change the flow rate.

Regarding claims 10-11, the step of expelling includes drawing a first amount of contrast media into the syringe (col. 6, lines 1-2) and expelling the first amount of the syringe and fill tube; or wherein the step of expelling and/or filling are performed by the contrast media injector automatically under the control circuitry of the injector (col. 6, line 30).

Regarding claims 12-17, similarly to rejection of claims 9-11 above, Wilson further discloses a method for changing contrast media containers during a syringe filling sequence, comprising the steps of pausing the syringe filling sequence of a syringe when a first contrast container is substantially emptied (col. 9, line 63+); replacing the first contrast container with a second contrast container; expelling substantially all air from a fill tube coupled between the syringe and second contrast container (col. 10, line 13); and thereafter, resuming filling the syringe from the second contrast container at a first rate wherein aeration of the contrast media is prevented (col. 5, line 63).

Regarding claims 18, 21-24, as best as understood, Wilson discloses a method comprising: drawing medical fluid into a syringe of a contrast media injector system at a first rate; expelling substantially all air from the fill tube (any air ejected, col. 2, line 11). It is noted that when expelling air out from the tube or syringe, one skill in the art to recognize that at least some of the medical fluid from the syringe has occurred to make sure all air out. Thereafter, the full filling occurs at a second rate (user will meter the amount and rate of contrast material injected, col. 5, lines 43-50 and col. 12, lines 20-22). Because the air being light than the contrast material, gathers near the top of syringe body. Therefore, the first rate of the step of expelling all air from the fill tube/syringe, including some medical fluid expelled from syringe must be slowly occur. For example, if the user applies big force, the plunger moves fast, (which is the first rate increase also), there will be air and all medical fluid/contrast material move out the syringe/fill tube which is the user does not want. Hence, the second rate is faster than the first rate. Wilson further discloses that flow rate changeable (col. 11, lines 25-30 or col. 12, lines 20-22). Therefore, one skill in the art would recognize that the second rate can be faster than first rate if the user wants to change the flow rate.

Regarding claim 19, the first rate is a rate sufficient to avoid aeration of the medical fluid (contrast fill operation repeated, col. 5, line 63+)

Regarding claim 20, Wilson discloses the claimed invention except for the step of drawing at least 20ml of the medical fluid in to the syringe. It would have been obvious to one having ordinary skill in the

art at the time of the invention was made to drawing 20ml of fluid, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

### ***Response to Arguments***

Applicant's arguments filed 11/15/07 have been fully considered but they are not persuasive.

Please see the rejection of claims 9-24 above for more details. Beside that, Examiner has clarified more specifically the points which are pertinent to applicant's current claims. Although Examiner understands Applicant's arguments regarding the differences between the prior art and the instant applicant, Examiner feels that these differences are not distinguish over the prior art, and that the current claims read on a conventional fill sequence. Examiner specifically points out in col. 5 where the "user will meter the amount and rate of contrast material injected..." (line 44+ and at line 61, "the contrast fill operation is performed during initial set up of system and maybe be repeated during operation of system whenever syringe body is running low on radiographic contrast material." (emphasis added). This indicates that before syringe is completely emptied, it is expelled of air and refilled, and this process may happened over again, and that the user can alter the rate and amount for the safety of the patient.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763